Stage 4 Harmonization
Official: May 1, 2023

Powdered Cellulose

Change to read:

▲Portions of the monograph text that are national *USP* text, and are not part of the harmonized text, are marked with symbols (♦) to specify this fact.▲ (NF 1-May-2023)

DEFINITION

Powdered Cellulose is purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant materials.

IDENTIFICATION

- **A. Procedure**

Iodinated zinc chloride solution: Dissolve 20 g of zinc chloride and 6.5 g of potassium iodide in 10.5 mL of water. Add 0.5 g of iodine, and shake for 15 min.

Sample: 10 mg

Analysis: Place the *Sample* on a watch glass, and disperse in 2 mL of *Iodinated zinc chloride solution*.

Acceptance criteria: The substance takes on a violet-blue color.

- **B. Procedure**

Sample: 0.25 g of Powdered Cellulose, accurately weighed to 0.1 mg

Analysis: Transfer the *Sample* to a 125-mL conical flask. Add 25.0 mL of water and 25.0 mL of 1.0 M cupriethylenediamine hydroxide solution. Immediately purge the solution with nitrogen, insert the stopper, and shake on a wrist action shaker, or other suitable mechanical shaker, until completely dissolved. Transfer an appropriate volume of the solution to a calibrated number 150 Cannon-Fenske, or equivalent, viscometer. Allow the solution to equilibrate at 25 ± 0.1° for NLT 5 min. Time the flow between the two marks on the viscometer, and record the flow time, t_1, in s.

Calculate the kinematic viscosity, $(KV)_1$, of the Powdered Cellulose taken:

$$\text{Result} = t_1 \times k_1$$

k_1 = viscometer constant (see *Viscosity—Capillary Methods* ⟨911⟩)

Obtain the flow time, t_2, for a 0.5 M cupriethylenediamine hydroxide solution using a number 100 Cannon-Fenske, or equivalent, viscometer.

Calculate the kinematic viscosity, $(KV)_2$, of the solvent:

$$\text{Result} = t_2 \times k_2$$

k_2 = viscometer constant

Determine the relative viscosity, η_{rel}, of the Powdered Cellulose specimen taken:

$$\text{Result} = (KV)_1/(KV)_2$$

$(KV)_1$ = kinematic viscosity of the Powdered Cellulose

$(KV)_2$ = kinematic viscosity of the solvent

Determine the intrinsic viscosity, $[\eta]_c$, by interpolation, using the *Intrinsic Viscosity Table* in the *Reference Tables* section.

Calculate the degree of polymerization, P:

$$\text{Result} = [95 \times [\eta]_c]/\{W_S \times [(100 - \%\text{LOD})/100]\}$$

W_S = weight of the Powdered Cellulose taken (g)

%LOD = value obtained from the test for *Loss on Drying*

Acceptance criteria: The degree of polymerization is greater than 440.

IMPURITIES

Change to read:

Inorganic Impurities

- **Residue on Ignition** ⟨281⟩

▲Sample: 1.0 g

Acceptance criteria: ▲ (NF 1-May-2023) NMT 0.3%, calculated on the dried basis

SPECIFIC TESTS

Change to read:

- ▲▲▲ (NF 1-May-2023)**Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** The total aerobic microbial count does not exceed 1000 cfu/g, the total combined molds and yeasts count does not exceed 100 cfu/g, and it meets the requirements of the tests for absence of *Staphylococcus aureus and Pseudomonas aeruginosa* and for absence of *Escherichia coli* and *Salmonella* species. ▲▲ (NF 1-May-2023)

- **pH** ⟨791⟩**:** The pH of the supernatant is 5.0–7.5. Mix 10 g with 90 mL of water, and allow to stand with occasional stirring for 1 h.

Change to read:

- **Loss on Drying** ⟨731⟩

▲Sample: 1.0 g

Analysis: ▲ (NF 1-May-2023) Dry ▲the *Sample* ▲ (NF 1-May-2023) at 105° for 3 h.

▲Acceptance criteria: ▲ (NF 1-May-2023)It loses NMT 6.5% of its weight.

- **Water-Soluble Substances**

Sample: 6.0 g

Analysis: Mix the *Sample* with 90 mL of recently boiled and cooled water, and allow to stand with occasional stirring for 10 min. Filter, with the aid of vacuum, discard the first 10 mL of the filtrate, and pass the filtrate through the same filter a second time, if necessary, to obtain a clear filtrate. Evaporate a 15.0-mL portion of the filtrate in a tared evaporating dish to dryness without charring, dry at 105° for 1 h, cool in a desiccator, and weigh.

Acceptance criteria: The difference between the weight of the residue and the weight obtained from a blank determination does not exceed 15.0 mg (1.5%).

- **Ether-Soluble Substances**

Sample: 10.0 g

Analysis: Place the *Sample* in a chromatography column having an internal diameter of about 20 mm, and pass 50 mL of peroxide-free ether through the column. Evaporate the eluate to dryness in a previously dried and tared evaporating dish with the aid of a current of air in a fume hood. After all the ether has evaporated, dry the residue at 105° for 30 min, cool in a desiccator, and weigh.

Acceptance criteria: The difference between the weight of the residue and the weight obtained from a blank determination does not exceed 15.0 mg (0.15%).

ADDITIONAL REQUIREMENTS

Change to read:

- ▲ (NF 1-May-2023)**Packaging and Storage:** Preserve in tight containers.▲ (NF 1-May-2023)

Change to read:

- ▲ (NF 1-May-2023)**Labeling:** The labeling indicates the nominal degree of polymerization value. Degree of polymerization compliance is determined using *Identification B*.▲ (NF 1-May-2023)

Page Information:

Not Applicable

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